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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,494	08/17/2001	Trang T. Le	PC31245	5208

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/932,494	LE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-89 and 95-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-89 and 95-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1-3, 10-13, 21, 22, 28-41, 46-48, 50-53, 62-83, 86-89 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Straub et al. US 6,395,300.

Mizumoto teaches a quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and additive agents (columns 13-19, claims 1-6). The blending ratio of high moldability and low moldability saccharides is from 2 to 20% by weight (column 7, lines 3-18). Drug is used in an amount of about 50% (column 10, lines 25-26). Drug includes both analgesic and anti-inflammatory agents (column 7, lines 13-15 and 39-41). The method for preparing the tablet is disclosed in columns 12-13 (see also examples). The composition further comprises lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed at column 11, lines 30-60.

Mizumoto does not expressly teach the claimed surfactant, as well as the claimed active agent such as celecoxib.

Straub teaches nsaid includes celecoxib (column 4, lines 55-58). Straub further teaches processing celecoxib with excipient such as wetting agent or surfactant into tablet suitable for oral administration (column 3, lines 5-6; and column 8, lines 10-14). Wetting agent or surfactant includes fatty acid ester, polyoxyethylene alkyl ether,

sodium lauryl sulfate, silicon dioxide, and combination of two or more (column 9, lines 3-67).

Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Mizumoto for nsaid including celecoxib in view of the teaching of Straub to obtain the claimed invention, because Straub teaches the equivalency of nsaid including ibuprofen, ketoprofen, flurbuprofen, and celecoxib, because Mizumoto teaches the use of stearic acid, polyethylene glycol *and the like* (column 13, lines 52-53), and because Mizumoto teaches non-steroidal anti-inflammatory such as ibuprofen, ketoprofen, flurbuprofen *and the like* (column 8, lines 13-15).

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Straub et al., and Jain et al. US 6,316,029.

Mizumoto is relied upon for the reason stated above. Mizumoto does not explicitly teach the claimed surfactant.

Jain teaches a process for preparing rapidly disintegrating solid oral dosage form, wherein the rapidly disintegrating dosage form comprises surfactant including sodium lauryl sulfate, and one or more pharmaceutical excipients such as silicon dioxide (column 7, lines 15-67; and column 8, lines 59-64). Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Mizumoto using the surfactant in view of the teaching of Jain to prepare a quick-dissolved formulation, because Jain teaches the use of surfactant as excipient in a quick disintegrating tablet

is well known pharmaceutical art (column 7, lines 2-33; and column 8, lines 14-18), and because Mizumoto teaches the use of excipients in the composition. The expected result would be a compressed tablet having good hardness, and dissolved quickly upon contact with fluid.

The examiner notes that the cited references are silent as to the claimed amounts of glidant, and surfactant in claims 18-20 and 23-25. However, it is the position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 04/17/07 have been fully considered but they are not persuasive.

Applicant argues Love does not teach the surfactants named above, nor does Love describe a solid fast-melt composition comprising one of these surfactants, as required by claim 1. The combination of Mizumoto and Love does not describe or suggest all the limitations of claim 1 or of the claims depending therefrom. Thus, the Office has not shown that claims 1-3, 10-13, 21, 22, 28-41, 46-48, 50-53, 62-83, 86-89, and 96-100 are prima facie obvious in view of Mizumoto and Love.

The rejection over Mizumoto in view of Love has been withdrawn in view of applicant's arguments.

Straub describes formulations of low solubility drugs in a porous matrix wherein the dissolution rate of the drug is enhanced when the matrix is contacted with an aqueous medium. Straub names at least 45 categories of drugs (see col. 4, line 22 through col. 7, line 20) contemplated for use in his compositions. Over 410 drugs are identified by name; one of these is celecoxib. Straub names over 100 drugs as preferred (see col. 7, line 45 through col. 8, line 9). Celecoxib is one of these drugs. As previously mentioned, Straub does not described any specific composition comprising celecoxib, and there is no indication whatsoever in Straub that celecoxib is particularly preferred.

However, celecoxib is a well-known anti-inflammatory drug, and Straub is one of the prior arts that confirmed this fact. Love is cited for the specific teaching that celecoxib is the preferred nsaid (column 9, lines 1-7). Accordingly, one of ordinary skill in the art would have been motivated to select celecoxib to prepare a composition as taught by Mizumoto, because Mizumoto teaches a process suitable to prepare an nsaid formulation.

Applicant argues that Straub does not specifically teach processing celecoxib with an excipient such as a wetting agent or surfactant. Rather, Straub mentions that wetting agents may in general be used to facilitate dissolution, but does not describe the specific combination of celecoxib with a wetting agent or surfactant. Thus, the combination of Mizumoto and Straub does not describe or suggest all the limitations of claim 1 or of the claims depending therefrom. Thus, the Office has not shown that

claims 1-3, 10-13, 21, 22, 28-41, 46-48, 50-53, 62-83, 86-89, and 96-100 are prima facie obvious in view of Mizumoto and Straub.

In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case, Straub teaches the use of surfactant and celecoxib is well known in pharmaceutical art. One of ordinary skill in the art would have been motivated to, by routine experimentation determine a suitable surfactant for a particular active agent depends on the solubility of the active agent. In response to applicant's argument of the specific combination of celecoxib with a wetting agent or surfactant. It is noted that the present claims recite a broad group with quite a large number of surfactants. There is no requirement of any one particular surfactant in combination with celecoxib.

Applicant argues that nothing in Jain suggests the need for formulating their poorly soluble drug and surface stabilizer with the saccharide having low moldability and the saccharide having high moldability required by Mizumoto. Jain's nanoparticulate compositions, and Mizumoto's intrabuccally dissolving compressed moldings comprising granules comprising a saccharide having low moldability and a saccharide having high moldability, would, at the very most, be seen as alternatives to one another, which one skilled in the art would have no reason or motivation to combine.

In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Jain is relied upon solely for the teaching of the use of sodium lauryl sulfate in a rapidly disintegrating solid oral dosage form is well known in pharmaceutical art. Thus, Jain provides a reason of expectation to motivate one of ordinary skill in the art to modify the quick dissolve tablet of Mizumoto to include surfactant, because Mizumoto teaches the desirability of using of pharmaceutically acceptable excipients in the dosage form.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER
Art Unit 1615